27. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which is raised to a multiply antigenic peptide comprising multiple copies of an isolated and purified peptide which comprises SEQ ID NO:4, SEQ ID NO:5, or both SEQ ID NO:4 and SEQ ID NO:5.

F8 Sub 67

34. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which is raised to a recombinant plant virus particle comprising at least one copy of an isolated and purified peptide comprising SEQ ID NO:4, SEQ ID NO:5, or both SEQ ID NO:4 and SEQ ID NO:5.

F9 Sub 67

43. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which specifically binds to the defined epitope bound by the antibody of claim 41.

F10 Sub 67

Remarks

The Amendments

Claims 1, 6, 15, 21, 27, 34, and 43 have been amended to recite that a specific binding protein is selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody. Applicants assert that the term "specific binding protein" is definite and enabled, however, in order to advance prosecution, Applicants have amended the claims. Support for the amendments can be found in the specification at, *inter alia*, page 17, lines 16 to 21. Applicants reserve the right to prosecute the non-amended claims in a continuing application.

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Claims 6, 27, and 34 have been amended to recite that a purified peptide is SEQ ID NO:4 or SEQ ID NO:5 or both, in order to advance prosecution. Support for the amendments occurs in the specification at, *inter alia*, page 28, lines 6-18 and page 10, line 24 through page 11, line 9. Applicants reserve the right to prosecute the non-amended claims in a continuing application.

Claims 8, 15, and 21 have been amended to state the position of the amino acid substitutions. Applicants believe that the non-amended claims are adequately enabled and described. However, in order to advance prosecution, Applicants have amended the claims. Support for the amendments can be found in the specification at, *inter alia*, page 10, lines 16-23, page 28, lines 6-18, and page 10, line 24 through page 11, line 9. Applicants reserve the right to prosecute the non-amended claims in a continuing application.

Applicants respectfully request entry of these amendments. The amendments place the case in condition for allowance or in better condition for appeal. The amendments were not earlier presented because Applicants believed the claims were in condition for allowance. The amended claims present no new matter and raise no new issue requiring further consideration or search.

The Rejection of Claims 6-11, 15-17, 21, 23, 27-30, 34-37 and 43 Under 35 U.S.C. §112, first paragraph

Claims 6-11, 15-17, 21, 23, 27-30, 34-37 and 43 stand rejected under 35 U.S.C. §112, first paragraph. Claims 9-11, 17, 23, 28, 30, 35 and 37 have been canceled; therefore, the rejection is moot as applied to these claims. Applicants respectfully traverse the rejection of the remaining claims.

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The Office Action asserts that "a specific binding protein that specifically binds an isolated and purified peptide comprising a leucine positioned two amino acids toward the amino terminus from a tyrosine-arginine pair" is not enabled by the specification. The claims have been amended to recite that a "specific binding protein" is "selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody." The claims have been further amended to recite that the specific binding protein binds to an isolated and purified peptide comprising SEQ ID NO:4 and/or SEQ ID NO:5.

Under 35 U. S. C. § 112, all that is required is that the specification describe the invention in such terms as to enable a person skilled in the art to make and use the invention. Thus, the specification must teach one skilled in the art how to make and use a claimed specific binding protein. The test of enablement is whether one reasonably skilled in the art (1) could make and use the invention (2) from the disclosures in the patent coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01.

One of skill in the art would understand how to make and use a specific binding protein of the invention. A specific binding protein is a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody. Each of these types of molecules are well known in the art. Furthermore, techniques for making these molecules with a given antigen are well known in the art.

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Working examples of the production and characterization of specific binding proteins of the invention are provided in the specification at, *inter alia*, page 24, lines 13- page 27, line 16 and Example 2. The specification also teaches that the specific binding proteins of the invention can be used as, *inter alia*, a treatment for or as prophylaxis for allergy symptoms. See, e.g., page 31, line 28 through page 32, line 2.

The Office Action further asserts that specific binding proteins that bind to conservative variants of purified peptides are not enabled. The amended claims recite that specific binding proteins of the invention specifically bind to purified peptides comprising SEQ ID NO:4, SEQ ID NO:5 or variants thereof. The variants comprise an amino acid substitutions at amino acid positions 4, 5, or both for SEQ ID NO:4 and at amino acid positions 5, 6, or both for SEQ ID NO:5. The specification clearly teaches that substitutions can be made within a core sequence of SEQ ID NO:4 or SEQ ID NO:5. Specifically, the specification teaches that a core peptide sequence comprises Leu-Xaa-Xaa-Tyr-Arg (SEQ ID NO:1). See page 10, lines 16-23. Both SEQ ID NOs:4 and 5 comprise the core sequence of SEQ ID NO:1 and can therefore comprise substitutions between the core Leu residue and the Tyr-Arg pair. The specification also provides assays that can be used to determine if a variant peptide specifically binds a specific binding protein of the invention. See Example 2.

Therefore, one of skill in the art could construct variants of SEQ ID NO:4 and SEQ ID NO:5 and could test and use specific binding proteins that bind to the variant peptides. Applicants respectfully request withdrawal of the rejection.

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The Rejection of Claims 1-2, 6-10, 17, 23, 27-30, 34-37, and 43 Under 35 U.S.C. §112, first paragraph

Claims 1-2, 6-10, 17, 23, 27-30, 34-37 and 43 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking written description. The Office Action asserts that the term "specific binding protein" lacks written description in the specification. Applicants respectfully traverse the rejection.

The amended claims are drawn to specific binding proteins that are selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody.

The standard for written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, the Applicant was in possession of the invention as now claimed. *See Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). The specification clearly defines specific binding proteins such that one of skill in the art would understand what is claimed. See e.g., page 17, lines 10-22.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 41 and 42 Under 35 U.S.C. §112, first paragraph

Claims 41 and 42 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. The Office Action asserts that the disclosure of an antigen used to generate a monoclonal antibody does not provide enablement for claims directed to that monoclonal antibody. Applicants respectfully traverse the rejection.

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First, the Office Action has not presented a *prima facia* case of lack of enablement. When rejecting a claim under the enablement requirement of §112 the Patent Office bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification. This includes providing sufficient reasons for doubting assertions. See MPEP §2164.04; *In re Wright*, 27 U.S.P.Q.2d 1510,1513 (Fed. Cir. 1993). "It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and reasoning which is inconsistent with the contested statement." See MPEP §2164.04; *In re Marzocchi*, 169 U.S.P.Q.367, 370 (CCPA 1971).

In the 10/24/00 Office Action, the Office appears to indirectly assert that the 8.H8 antibody is not known and readily available to the public or obtainable by a repeatable method set forth in the specification. The 5/21/01 Office Action merely states that it disagrees with the Applicant's argument that the claims are enabled. The Office Action has not provided a reasonable explanation as to why the teachings of the specification including, for example, the provision of the antigen sequence used to raise 8.H8 monoclonal antibodies, do not enable the claims. The Office Action, instead, relies on a bald assertion that the claims are not enabled by the specification.

Applicants remind the Office that the Office must accept at being true the statements supporting enablement unless there is an objective reason, usually supported with documentary evidence to question them.

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Second, despite the failure of the Office Action to establish a *prima facia* case of non-enablement, the claims are indeed enabled. Under 35 U. S. C. § 112, all that is required is that the specification describe the invention in such terms as to enable a person skilled in the art to make and use the invention. Thus, the specification must teach one skilled in the art how to make and use a 8H.8 monoclonal antibody. The test of enablement is whether one reasonably skilled in the art (1) could make and use the invention (2) from the disclosures in the patent coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01. "The determination of what constitutes undue experimentation is a given case requires the application of a standard of reasonableness, having due regard of the nature of the invention and the state of the art." *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (citing *Ansul Co. v. Uniroyal, Inc.*, 169 U.S.P.Q. 759, 762-63 (2d Cir. 1971). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id.*

Claims 41 and 42 recite a monoclonal antibody that is 8H.8. The specification discloses that a 8H.8 monoclonal antibody can be made by "immunizing mice with a shortened version of exon 3 of the canine IgE molecule, designated exon 3a. Exon 3a contains the C-terminal 71 amino acids of the full length exon 3." See specification, page 24, lines 13-17. The specification also teaches that the sequence of canine IgE, exon 3 was known in the art at the time of filing of the instant application and provides citations

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to the sequence. See specification, page 4, line 27 through page 5, line 6. The steps in the production of monoclonal antibodies from an antigen is well known to those of skill in the art and was even outlined by the Federal Circuit thirteen years ago. See, *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

Given the specification, and information known in the art at the time of filing, one of skill in the art could make and use a 8H.8 monoclonal antibody without undue experimentation. Furthermore, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991).

The Office Action has failed to provide a *prima facia* case of non-enablement. The claims are enabled by the specification and Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 17, 23, 30, and 37 Under 35 U.S.C. §112, second paragraph

Claims 17, 23, 30, and 37 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Claims 17, 23, 30, and 37 have been canceled; therefore the rejection is moot as applied to these claims. Applicants respectfully request withdrawal of the rejection.

The Rejection of Claim 41 Under 35 U.S.C. §112, second paragraph

Claim 41 stands rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Applicants respectfully request withdrawal of the rejection.

The Office Action alleges that the term "8H.8" is indefinite. The Office Action alleges that a laboratory designation cannot be considered a universal designation and can be variable. However, the test for definiteness is "whether those skilled in the art would

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understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). "A claim need not describe the invention, such description is the role of the disclosure portion of the specification, not the role of the claims." *Id.* at 1575.

One of skill in the art would understand that the term "8H.8" when claim 41 is read in light of the specification. The specification teaches that a 8H.8 monoclonal antibody is an antibody derived by immunizing mice with canine IgE exon 3a, which contains the C-terminal 71 amino acids of the full length exon 3. See specification, page 24, lines 13-20. Therefore, claim 41 is definite when read in light of the specification, which clearly discloses the meaning of the term.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 1 and 2 Under 35 U.S.C. §102(b)

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 95/31728. Applicants respectfully traverse the rejection.

Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 3 USPQ2d 1766 (Fed. Cir. 1987). Claim 1 of the present invention is drawn to a specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody that specifically binds to a native canine B cell-bound IgE, and that does not bind to IgE when the IgE is bound to a receptor on a mast cell. Claim 2 recites the

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specific binding protein of claim 1 wherein the B cell-bound IgE is IgE expressed on the surface of a canine B cell.

WO 95/31728 is a patent application drawn to methods of detecting cancer involving fragments of cytokeratin 18 and corresponding antibodies. WO 95/31728 neither teaches nor suggests a specific binding protein that specifically binds to a native canine B cell-bound IgE. WO 95/31728 furthermore neither teaches nor suggests the specific binding protein does not bind to IgE when the IgE is bound to a receptor or mast cell.

WO 95/31728 further does not inherently teach specific binding proteins with these claimed properties. The Office Action asserts that the protein sequences on page 6, lines 16 and 27 and described on page 9, lines 3-6 inherently comprise the properties of the claimed specific binding proteins. The WO 95/31728 protein sequences clearly do not comprise the motifs of the present invention as shown below:

WO 95/31828	Leu Arg Glu Val Glu Ala Arg Tyr Ala Leu Gln Met Glu Gln Leu Asn Gly Ile Leu Leu His
A motif of present invention	**Leu Xaa Xaa Tyr Arg**

It is clear the WO/9531828 does not inherently teach or suggest the subject matter of claims 1 and 2 as the Office Action asserts. The cited reference does not teach or suggest a motif disclosed in the present application as specific for B cell bound IgE, but not mast cell bound IgE.

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The cited reference does not teach or suggest, directly or indirectly, each and every element of claims 1 and 2. Therefore, Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 1 and 2 Under 35 U.S.C. §102(b)

Claims 1 and 2 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,321,123 (the '123 patent). Applicants respectfully traverse the rejection.

The '123 application teaches polypeptides and antibodies that inhibit protein S binding to C4B binding protein. The '123 patent neither teaches nor suggests a specific binding protein that specifically binds to a native canine B cell-bound IgE. The '123 patent furthermore neither teaches nor suggests the specific binding protein does not bind to IgE when the IgE is bound to a receptor or mast cell.

The '123 patent also does not inherently teach specific binding proteins with these claimed properties. The Office Action asserts that the protein sequences in Table 1, specifically PSP-7 and PSP-16, inherently comprise the properties of the claimed specific binding proteins. The '123 patent protein sequences clearly do not comprise the motifs of the present invention as shown below:

'123 Patent PSP-7	Cys Pro Glu Gly Tyr Arg Tyr Asn Leu Lys Ser Lys Ser Cys
'123 Patent PSP-16	Ser Pro Glu Gly Tyr Arg Tyr Asn Leu Lys Ser Lys Ser Ser Glu
A motif of present invention	Leu Xaa Xaa Tyr Arg

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It is clear the '123 patent does not inherently teach or suggest the subject matter of claims 1 and 2 as the Office Action asserts. The cited reference does not teach or suggest a motif disclosed in the present application as specific for B cell bound IgE, but not mast cell bound IgE.

The cited reference does not teach or suggest, directly or indirectly, each and every element of claims 1 and 2. Therefore, Applicants respectfully request withdrawal of the rejection.

The Rejection of Claim 1 Under 35 U.S.C. §112, first paragraph

Claim 1 stands rejected under 35 U.S.C. §112, first paragraph as allegedly lacking written description. The Office Action asserts that the amendment deleting the phrase "free or" from claim 1 in the last response constitutes new matter. Applicants respectfully traverse the rejection.

The instant application teaches that a 8H.8 antibody has a low affinity for soluble (i.e., free) native canine IgE and that the region within native IgE recognized by 8H.8 may be partially hidden, particularly when the IgE is in serum. See page 27, lines 9-29. The specification further teaches a 8H.8 antibody:

> would preferentially bind to IgE on memory B cells rather than to IgE in solution. Moreover, 8H.8 has a low binding affinity for IgE when bound by Fc receptor on mast cells. Page 28, lines 1-5.

The specification clearly contemplates specific binding proteins that specifically bind native canine B cell-bound IgE, but has only low affinity for free IgE or IgE that is bound to a receptor on a mast cell. As such, the amendment deleting the phrase "free IgE" does not constitute new matter.

Applicants respectfully request withdrawal of the rejection.

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The Rejection of Claims 6, 27, and 34 Under 35 U.S.C. §112, first paragraph

Claims 6, 27, and 34 stands rejected under 35 U.S.C. §112, first paragraph as allegedly lacking written description. The Office Action asserts that the phrase "two amino acids toward the amino terminus," which was added to the claims in the last response constitutes new matter. Applicants respectfully traverse the rejection.

Claims 6, 27, and 34 have been amended and do not recite the material alleged to be new matter. Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the above remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Date: Oct 19, 2001

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APPENDIX A
Marked-Up Version of Amended Claims to Show Changes Made

1. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which specifically binds to native canine B cell-bound IgE, and which does not bind to IgE when the IgE is bound to a receptor on a mast cell.

6. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which specifically binds to an isolated and purified peptide comprising [a leucine positioned two amino acids toward the amino terminus from a tyrosine-arginine pair] SEQ ID NO:4.

8. (Twice Amended) The specific binding protein of claim [7] 1[wherein at least one amino acid substitution is [Xaa is] an amino acid with an aromatic ring.

15. (Twice Amended) [An antibody] A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody which [is raised to] specifically binds an isolated and purified peptide comprising an amino acid sequence which comprises Thr-Leu-Leu-Glu-Tyr-Arg-Met (SEQ ID NO:4), or a [conservative] variant thereof, wherein the variant comprises an amino acid substitution at amino acid positions 4, 5, or both 4 and 5.

16. (Amended) The [antibody] specific binding protein of claim 1[that binds to a defined epitope.

21. (Twice Amended) [An antibody] A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which [is raised to] specifically binds an isolated and purified peptide comprising an amino acid sequence which comprises Gly-Met-Asn-Leu-Thr-Trp-Tyr-Arg-Glu-Ser-Lys (SEQ ID NO:5), or a [conservative] variant thereof, wherein the variant comprises an amino acid substitution at amino acid position number 5, 6, or both 5 and 6.

22. (Amended) The [antibody] specific binding protein of claim 2[that binds to a defined epitope.

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27. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which is raised to a multiply antigenic peptide comprising multiple copies of an isolated and purified peptide which comprises [a leucine positioned two amino acids toward the amino terminus from a tyrosine-arginine pair] SEQ ID NO:4, SEQ ID NO:5, or both SEQ ID NO:4 and SEQ ID NO:5.

34. (Twice Amended) A specific binding protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which is raised to a recombinant plant virus particle comprising at least one copy of an isolated and purified peptide comprising [a leucine positioned two amino acids toward the amino terminus from a tyrosine-arginine pair] SEQ ID NO:4, SEQ ID NO:5, or both SEQ ID NO:4 and SEQ ID NO:5.

43. (Twice Amended) A [recombinant] specific binding [molecule] protein selected from the group consisting of a monoclonal antibody, a polyclonal antibody, an antigen-binding fragment of a monoclonal antibody, an antigen-binding fragment of a polyclonal antibody, a hybrid antibody, and a single chain antibody, which specifically binds to the defined epitope bound by the antibody of claim 41.

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